DEPARTMENT OF HEALTH AND HUMAN SERVICES

93707d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

November 13, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 03-03

Ryan R. DeLuca, Owner
Higher Power Nutrition
851 Vista Avenue
Boise, ID 83705

WARNING LETTER

Dear Mr. DeLuca:

This letter is written in reference to your firm's marketing of the products Higher Power Nutrition Test-4 Blast, TestroGel, Deca Derm, MedLean Andro SportsCreme, and Pharmalogic XRX ANDROGENX Nasal Andro, each of which contains androstenedione and/or androstenediol. Your Internet web site, http://www.bodybuilding.com, from which these products may be ordered, states, for example, "...Higher Power Nutrition Test-4 Blast...experience lean muscle mass and strength gains...boosting testosterone levels...," "...TestroGel...increased strength...increased sexual drive...," "...Deca Derm...enhanced strength...enhanced lean tissue gain...," "...MedLean Andro SportsCreme...restore optimal levels of testosterone...sexual vitality...," and "...Pharmalogic XRX ANDROGENX Nasal Andro...testosterone increase...".

Higher Power Nutrition Test-4-Blast, TestroGel, Deca Derm, and MedLean Andro SportsCreme are topically applied for transdermal absorption to achieve their intended effect. Pharmalogic XRX ANDROGENX Nasal Andro is an intranasal product. These products cannot be dietary supplements because they are not intended for ingestion since they are topical or intranasal products that are intended to bypass the alimentary canal by direct absorption through the skin or nasal mucosa. The Act defines the term, "dietary supplement" in Section 201(ff)(2)(A)(i) to mean a product that is "...intended for ingestion...". Consequently, a product that is not intended for ingestion cannot meet the definition of "dietary supplement".

Based on their intended uses, to affect the structure or any function of the body of man, these products are drugs within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). As drugs, the labeling claims made for these products subject them to the requirements for new drugs [Section 201(p) of the Act] because there is no evidence that these products are generally recognized as safe and effective for their claimed uses. Further, all

transdermal drug delivery products are new drugs because of the newness of the dosage or the method or duration of administration or application suggested in the labeling (See Title 21 of the Code of Federal Regulations, Part 310.3). Under Section 505 of the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for such drug. Because your products are not the subjects of approved NDA's, they may not be marketed in the United States and their continued distribution violates Section 505 of the Act.

This letter is not intended to be an all-inclusive review of your Internet web site nor all labeling and products your firm markets. The violation described above is not intended to be an all inclusive list of violations concerning your firm and its products. It is your responsibility to ensure that all products marketed by your firm, including other products containing androstenedione and/or androstenediol, are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the FDA without further notice. The Act provides for seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, Seattle District Office, 22201 23rd Drive SE, Bothell, Washington, 98021-4421, to the attention of Lisa M. Elrand, Compliance Officer. Should you have any questions concerning this letter, Ms. Elrand can be contacted by telephone at (425) 483-4913.

Sincerely,

for Charles M. Breen
District Director

cc: ISDH with disclosure statement